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Registration Decision RD2013-16

Chlorfenapyr

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Overview

Registration Decision for Chlorfenapyr

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of Chlorfenapyr Technical Insecticide, Mythic Insecticide and Pylon Miticide Insecticide, containing the technical grade active ingredient chlorfenapyr. Mythic Insecticide is intended for use in limited applications to the exterior of buildings against various pests and as a pre-construction and post-construction termiticide. Pylon Miticide Insecticide is intended for use on greenhouse ornamentals and greenhouse fruiting vegetables.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document[1] Proposed Registration Decision PRD2013-01, *Chlorfenapyr*. This Registration Decision[2] describes this stage of the PMRA's regulatory process for chlorfenapyr and summarizes the Agency's decision, the reasons for it and provides, in Appendix I, a summary of comments received during the consultation process as well as the PMRA's response to these comments. This decision is consistent with the proposed registration decision stated in PRD2013-01.

For more details on the information presented in this Registration Decision, please refer to PRD2013-01, which contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[3] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value[4] when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

3 "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

4 "Value" as defined by subsection 2(1) of the *Pest Control Products Act*: "the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact."

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

What Is Chlorfenapyr?

Chlorfenapyr is a member of the pyrrole class of insecticides (Group 13) and is the active ingredient contained in the commercial class products Pylon Miticide Insecticide and Mythic Insecticide. Pylon Miticide Insecticide is an insecticide/acaricide/nematicide for use on greenhouse ornamentals and some greenhouse fruiting vegetables. Mythic Insecticide is for use in limited applications to the exterior of buildings against various pests and as pre-construction and post-construction termiticide.

Health Considerations

Can Approved Uses of Chlorfenapyr Affect Human Health?

Products containing chlorfenapyr are unlikely to affect your health when used according to label directions.

Potential exposure to chlorfenapyr may occur through the diet, when handling and applying the product, or when entering an area that has been treated with the product. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed. The health effects noted in animals occur at doses more than 100-times higher (and often much higher) than levels to which humans are normally exposed when pesticide products are used according to label directions.

In laboratory animals, the technical grade active ingredient chlorfenapyr was of high acute toxicity by the oral route; consequently, the hazard signal words "DANGER POISON" are required on the label. Chlorfenapyr was of low acute toxicity by the dermal route, and moderately toxic by the inhalation route. Chlorfenapyr was mildly irritating to the eyes, non-irritating to skin and did not cause an allergic skin reaction.

The acute toxicity of the end-use products Mythic Insecticide and Pylon Miticide Insecticide was moderate by the oral and inhalation routes; consequently, the hazard signal words "WARNING POISON" are required on the product labels. The acute toxicity of the end-use products was low by the dermal route. The end-use products were non-irritating to the eye, minimally irritating to the skin, and did not cause allergic skin reactions.

There was no evidence to suggest that chlorfenapyr damaged genetic material. Health effects in animals given repeated doses of chlorfenapyr included reductions in body weight, body weight gain and food consumption, deaths, and effects on the liver, blood, and nervous system. Chlorfenapyr also caused tumours originating from the blood production system in rats.

When chlorfenapyr was given to pregnant or nursing animals, deaths were observed in offspring at doses that were not toxic to the mother, indicating that the young were more sensitive to chlorfenapyr than the adult animal. The risk assessment takes this sensitivity into account in determining the allowable level of human exposure to chlorfenapyr.

Deaths occurred in adult animals at lower doses when chlorfenapyr was given by the inhalation route compared to the oral route. Toxicity via the inhalation route has not been characterized in developing fetuses or in young animals, and therefore extra protective factors were applied in the risk assessment to further reduce the allowable level of human exposure to chlorfenapyr via the inhalation route.

The risk assessment protects against the effects of chlorfenapyr by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests.

Residues in Food

Dietary risks from food are not of concern.

Dietary intake estimates based on the greenhouse residue trials, revealed that the children between 1–2 years old, the subpopulation which would ingest the most chlorfenapyr relative to body weight, are expected to be exposed to less than 21% of the acute reference dose, based on an intermediate refinement of the exposure. For the basic chronic dietary risk the children between 3–5 years old are expected to be the most affected subpopulation with an estimated exposure of 21% of the acceptable daily intake. Based on these estimates, the acute and chronic dietary risk from chlorfenapyr are not of concern for all population sub-groups.

The lifetime cancer risk estimate was further refined using American monitoring data. Based on this data, the lifetime cancer risk is not of concern (9×10^{-8}).

The *Food and Drugs Act* prohibits the sale of adulterated food, that is, food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Residue trials conducted throughout Canada and the United States using chlorfenapyr on fruiting vegetables were acceptable. The proposed MRLs for this active ingredient can be found in the Science Evaluation section of this Consultation Document.

Risks in Residential and Other Non-Occupational Environments

Residential exposure after a termiticide treatment using Mythic Insecticide is not expected to result in unacceptable risk when used according to label directions. Residential exposure to individuals contacting treated outdoor surfaces is not expected to result in unacceptable risk when Mythic Insecticide is used according to label directions.

Residential exposure is not expected from use of Pylon Miticide Insecticide.

Occupational Risks From Handling Mythic Insecticide and Pylon Miticide Insecticide

Occupational risks are not of concern when Mythic Insecticide or Pylon Miticide Insecticide is used according to the label directions, which include precautionary measures, limitations on equipment usage and/or reductions in application rates.

Farmers and custom applicators who mix, load or apply Pylon Miticide Insecticide as well as workers re-entering freshly treated greenhouses can come in direct contact with product residues on the skin or through inhalation. Therefore, the label specifies that anyone mixing/loading and applying Pylon Miticide Insecticide must wear coveralls over long-sleeved shirt, long pants, shoes and socks and chemical resistant gloves. The label also requires that workers not enter the treated greenhouse for 12 hours after application. Based on the assessment of acute inhalation hazards, workers mixing/loading/applying Pylon Miticide Insecticide must wear a respirator. Taking into consideration these precautionary statements, restrictions on the maximum application rate and reduced number of applications, limiting application equipment and limiting the amount of product used, risks to these individuals are not of concern.

Pest control operators (PCOs) who mix, load, and apply Mythic Insecticide can come into direct contact with product residues on the skin or through inhalation. Therefore, the label specifies that anyone mixing/loading and applying Mythic Insecticide must wear a long-sleeved shirt, long pants, shoes and socks, and chemical resistant gloves. Similar to the Pylon Miticide Insecticide, the assessment of acute inhalation hazards warrants that mixers, loaders and applicators wear a respirator when applying in confined spaces. PCOs using mechanically pressurized handheld equipment cannot mix/load and apply more than 80 L of product per day. The label also requires that no contact with treated areas can occur until sprays have dried.

For bystanders, exposure is considered negligible. Therefore, health risks to bystanders are not of concern.

Environmental Considerations

What Happens When Chlorfenapyr Is Introduced Into the Environment?

Chlorfenapyr is toxic to pollinators such as honeybees and beneficial arthropods (i.e. predatory mite and parasitic wasp). Chlorfenapyr is persistent and immobile in soil, and is persistent in aquatic sediment. Label instructions that caution users about the potential effects of chlorfenapyr on non-target beneficial insects are required.

Due to the intended use pattern for Mythic Insecticide (indoor and structural uses) and Pylon Miticide Insecticide (greenhouse uses), limited environmental exposure is expected. However, once it enters the terrestrial environment, it is persistent and immobile. It is stable to hydrolysis and forms only minor phototransformation and biotransformation products on soil. Chlorfenapyr phototransforms in water, with the production of one major aquatic phototransformation product (CL 357806).

Chlorfenapyr is persistent in aquatic systems, undergoing slow biotransformation, with the production of one major aquatic biotransformation product under both aerobic and anaerobic conditions (CL 312094). Based on its low volatility (low vapour pressure and Henry's law constant), chlorfenapyr residues are not expected in the air, nor is long-range aerial transport expected.

Chlorfenapyr may adversely affect non-target terrestrial invertebrates, such as pollinators and beneficial arthropods. Therefore, toxicity statements as well as instructions that direct users not to apply the product in the presence of these sensitive and important insects, are specified on the product label.

Value Considerations

What Is the Value of Pylon Miticide Insecticide?

Pylon Miticide Insecticide controls a variety of arthropod and nematode pests on ornamentals and suppresses a variety of arthropod pests on some greenhouse fruiting vegetables.

Chlorfenapyr is a new mode of action for use on greenhouse ornamentals and greenhouse fruiting vegetables, and will therefore provide a new tool for rotation with currently registered products in other mode of action groups. Pylon Miticide Insecticide is the only product registered for suppression of foliar nematodes on greenhouse ornamentals and tomato hornworm and tobacco budworm on greenhouse fruiting vegetables.

What Is the Value of Mythic Insecticide?

Mythic Insecticide kills a variety of arthropod pests when applied as a crack and crevice or spot treatment to the exterior of buildings where pests may enter (for example, doors, windows, around vents). Mythic Insecticide is also a pre- and post-construction termiticide.

The active ingredient in Mythic Insecticide has a different mode of action than currently registered pest control products used in structural pest control and will contribute to resistance management. It is also an alternative to older chemistries, such as organophosphates and carbamates, registered for the same uses. In addition, Mythic Insecticide will be an additional product that can be used against structural pests, such as subterranean termites, for which there are few products registered in Canada.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures are on the label of Mythic Insecticide and Pylon Miticide Insecticide to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

Because there is a concern with workers coming into direct contact with Mythic Insecticide and Pylon Miticide Insecticide on the skin or through inhalation of spray mists, anyone mixing, loading and applying these products must wear a long-sleeved shirt, long pants, shoes and socks, and chemical resistant gloves. In addition, for Pylon Miticide Insecticide, mixers/loaders and applicators must wear coveralls. The label also requires that workers not enter the treated greenhouses for 12 hours after application. The use pattern for Pylon Miticide Insecticide applied to greenhouse vegetables will be reduced to a single application per crop cycle at 0.075 g a.i./L assuming a maximum spray volume of 1000 L. Pylon Miticide Insecticide cannot be applied with mechanically pressurized handheld equipment to greenhouse ornamentals. The maximum spray volume for greenhouse ornamentals is 1500 L/ha. For Mythic Insecticide, workers must not mix, load and apply more than 80L of product/day with mechanically pressurized handheld equipment. Further to this, based on the assessment of acute inhalation hazards, workers mixing/loading Mythic Insecticide must wear a respirator and workers mixing/loading/applying Pylon Miticide Insecticide must wear a respirator.

Environment

Mitigative environmental label statements are required on all Pylon Miticide Insecticide labels. These statements will indicate the toxicity of chlorfenapyr to pollinators and beneficial arthropods, and direct users not to apply the product in their presence.

Other Information

The relevant test data on which the decision is based (as referenced in this document) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

Any person may file a notice of objection[5] regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management section of Health Canada's website (Request a Reconsideration of Decision, www.hc-sc.gc.ca/cps-spc/pest/part/protect-proteger/publi-regist/index-eng.php#rrd) or contact the PMRA's Pest Management Information Service.

[5]As per subsection 35(1) of the *Pest Control Products Act*.

Appendix I Comments and Responses

1. Comments received offering full support of the Proposed Registration Decision

As part of Health Canada, the PMRA strives to protect the health and environment of Canadians while providing improved access to innovative pesticides for Canadians in an effective and transparent manner.

References

A. List of Studies/Information Submitted by Registrant

1.0 Chemistry

PMRA Document Number	Reference
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1859694	2009, Minor Modification to Manufacturing Process and Starting materials, DACO: 2.11.2, 2.11.3 CBI
1859697	2002, Product chemistry data requirements for the manufacturing-use product, Technical AC 303,268: OPPTS 830.1670, Description of the formation of impurities, DACO: 2.11.4 CBI
1859698	2001, Compositional analysis of chlorfenapyr (AC 303,630, BAS 306 I) technical grade active ingredient manufactured at [CBI removed] in support of registration with world-wide regulatory auth, DACO: 2.12.
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1921525	1993, Validation of the High Performance Liquid Chromatographic Method M-2066.01 to Assay for CL 303,268 in Pirate Technical Grade Active Ingredient (TGAI), DACO: 2.13.1 CBI
1921528	1993, Validation of the High Resolution Gas Chromatographic (HRGC) Method M-2272 to Assay for Impurities in Pirate Technical Grade Active Ingredient (TGAI), DACO: 2.13.1 CBI
1921532	1994, Validation of Gas Chromatographic Method M-2368 for Analysis of Residual Isopropanol and Xylenes in CL 303,630 Technical Grade Active Ingredient (TGAI), DACO: 2.13.1 CBI
1859699	1995, Identification of the Impurities in AC 303,630 technical grade active ingredient, DACO: 2.13.2 CBI
1939503	2010, Plant data, DACO: 2.13.3 CBI
1859701	1994, Product chemistry determinations for CL 303,630 purified (color, physical state, odor, density), DACO: 2.14.1, 2.14.2, 2.14.3, 2.14.6

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1859714	1991, AC 303,630: Determination of the melting point, DACO: 2.14.4
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1859720	1997, AC 303630: Determination of the vapor pressure, DACO: 2.14.9
1859707	1995, AC 303,630: n-octanol/water partition, DACO: 2.14.11
1859709	1994, CL 303,630 spectral database., DACO: 2.14.12 CBI
1859721	1993, Pirate technical (AC 303,630) - Explodability, DACO: 2.16
1859711	1994, Pirate technical (AC 303,630) - Storage stability, corrosion characteristics, and stability at normal and elevated temperatures, DACO: 2.14.13, 2.14.14
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1859940	1993, Pirate and Stalker insecticides: Validation of a chromatographic method for the determination of the active ingredient CL 303,630 in suspension concentrate (SC) formulations, DACO: 3.4.1 CBI
1859941	1993, Pirate (AC303,630 3SC) insecticide product chemistry: Physical and chemical characteristics, DACO: 3.5
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2.0 Human and Animal Health

1859722	2009, DACO 4.1 Toxicology Summary, DACO: 4.1
1859724	1993, Oral LD_{50} study in albino rats with AC 303,630 technical, DACO: 4.2.1
1859725	1994, Oral LD_{50} study in albino rats with AC 312,094 technical, DACO: 4.2.1
1859726	1994, Oral LD_{50} study in albino mice with AC 303,630 technical, DACO: 4.2.1
1859727	1992, Dermal LD_{50} study in albino rabbits with AC 303,630 technical, DACO: 4.2.2
1859728	1993, Acute inhalation toxicity study with AC 303,630 in rats, DACO: 4.2.3
1859729	1993, Eye irritation study in albino rabbits with AC 303,630 technical, DACO: 4.2.4
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1859737	1993, AC 303,630: A 13-week dietary toxicity study in the albino rat, DACO: 4.3.1
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1859744	1994, A one-year dietary neurotoxicity study with AC 303,630 in rats, DACO: 4.3.2
1859754	1994, One year dietary toxicity study with AC 303,630 in purebred Beagle dogs, DACO: 4.3.2
1859755	1991, AC 303,630: A 28-day rat feeding study, DACO: 4.3.3
1859756	1991, AC 303,630: A 28-day mouse feeding study, DACO: 4.3.3
1859757	1993, 90-day dietary toxicity study with AC 303,630 in purebred Beagle dogs, DACO: 4.3.4
1859761	1993, A 28-day dermal toxicity study with AC 303,630 in rabbits, DACO: 4.3.5
1859763	1994, A 28-day dermal toxicity study with AC 303,630 3SC in rabbits, DACO: 4.3.5
1859765	2005, Repeated dose 28-day dermal toxicity study in Wistar rats, DACO: 4.3.5
1859768	2005, BAS 306 I - Subchronic 90-day inhalation study in Wistar rats dust aerosol exposure, DACO: 4.3.6

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1859774	1994, A chronic dietary toxicity and oncogenicity study with AC 303,630 in mice, DACO: 4.4.4
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1859777	1994, A pilot dietary reproduction study in rats with AC 303,630, DACO: 4.5.1
1859778	1994, A two-generation (one-litter) reproduction study with AC 303,630 in rats, DACO: 4.5.1
1859780	1996, An acute neurotoxicity study with AC 303,630 in rats, DACO: 4.5.12
1859782	2006, BAS 306 I - Developmental neurotoxicity study in Wistar rats - Oral administration to the dams and pups (gavage), DACO: 4.5.14
1859783	1993, An oral developmental toxicity (embryo-fetal toxicity / teratogenicity) definitive study with AC 303,630 in rats, DACO: 4.5.2
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3.0 Value

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